Quidel Receives CE Mark for Its New Sofia(R) Fluorescent Immunoassay for Diagnosis of Pneumococcal Pneumonia and Pneumococcal Meningitis

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SAN DIEGO, CA -- (Marketwired) -- 01/25/16 -- ***Quidel Corporation*** (NASDAQ: QDEL), a provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today that it has received the CE Mark for Quidel's Sofia® S. pneumoniae Fluorescent Immunoassay (FIA) for use with the Sofia Fluorescent Immunoassay Analyzer. The Sofia S. pneumoniae FIA enables the rapid, qualitative detection of *Streptococcus pneumoniae* antigen in the urine of patients with pneumonia and in the cerebral spinal fluid (CSF) of patients with meningitis. Test results aid in the diagnosis of both pneumococcal pneumonia and pneumococcal meningitis.

Streptococcus pneumoniae (SPN) is the leading cause of community-acquired pneumonia.[1, 2] SPN can cause a wide spectrum of illnesses from upper respiratory tract infection to invasive pneumococcal disease. SPN infection is also associated with high mortality -- an estimated 1.6 million people die of pneumococcal diseases each year worldwide and approximately 1 million of these deaths are in children under five years of age.[3]

Pneumococci also cause over 50% of all cases of bacterial meningitis in the United States.[4] Bacterial meningitis is usually severe, leading to complications such as brain damage, hearing loss, or learning disabilities. Antibiotic treatment for bacterial meningitis can be effective and should be started as soon as possible to limit or prevent these complications and to reduce the risk of death from meningitis.[5]

The Sofia S. pneumoniae FIA is an immunofluorescence-based lateral flow test that supports the diagnosis of pneumococcal pneumonia or pneumococcal meningitis in 10 minutes. The CE mark allows Quidel to launch the new Sofia assay in advance of the peak season in Europe and in other locations outside the United States. The product is currently not for sale in the U.S.

"We are very pleased to receive CE Mark for our Sofia S. pneumoniae FIA for the European market," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "The combination of Sofia tests for the two leading community acquired pneumonias in Europe -- Streptococcus pneumonia and Legionella pneumophila -- both using the same specimen, both giving results in 10 minutes, and both available in the E.U. opens up an exciting new market opportunity for us that will enhance our already successful and expanding Sofia platform usage around the world."

Quidel currently offers four other Sofia assays with the CE Mark: Influenza A+B, RSV, Strep A+ and Legionella.

1. Etiology of Community-Acquired Pneumonia: Increased Microbiological Yield with New Diagnostic Methods, N. Johansson et al., CID 2010:50.

2. Guidelines for management of community-acquired pneumonia in adults, G. Lopardo et al., Medicina (B Aires). 2015; 75(4):245-257.

3. Streptococcus pneumoniae nasopharyngeal colonisation in children aged under six years with acute respiratory tract infection in Lithuania, V Usonis et al, Eurosurveillance, Volume 20, Issue 13, 02 April 2015.

4. Pneumococcal Disease: Epidemiology and Prevention of Vaccine-Preventable Diseases, CDC The Pink Book: 13th Edition (2015).

5. Bacterial meningitis in the United States, 1998-2007, M. C. Thigpen et al., N Engl J Med. 2011

About Quidel Corporation

Quidel Corporation serves to enhance the health and well-being of people around the globe through the development of diagnostic solutions that can lead to improved patient outcomes and provide economic benefits to the healthcare system. Marketed under the QuickVue®, D3® Direct Detection and Thyretain® leading brand names, as well as under the new Sofia®, AmpliVue® and Lyra® brands, Quidel's products aid in the detection and diagnosis of many critical diseases and conditions, including, among others, influenza, respiratory syncytial virus, Strep A, herpes, pregnancy, thyroid disease and fecal occult blood. Quidel's research and development engine is also developing a continuum of diagnostic solutions from advanced lateral-flow and direct fluorescent antibody to molecular diagnostic tests to further improve the quality of healthcare in physicians' offices and hospital and reference laboratories. For more information about Quidel's comprehensive product portfolio, visit quidel.com.

This press release contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, fluctuations in our operating results resulting from seasonality, the timing of the onset, length and severity of cold and flu seasons, government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses, adverse changes in competitive conditions in domestic and international markets, changes in sales levels as it relates to the absorption of our fixed costs, lower than anticipated market penetration of our products, the reimbursement system currently in place and future changes to that system, and changes in economic conditions in our domestic and international markets, the quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors and changes in the healthcare market and consolidation of our customer base; our development and protection of intellectual property; our development of new technologies, products and markets; our reliance on a limited number of key distributors; our reliance on sales of our influenza diagnostics tests; our ability to manage our growth strategy, including our ability to integrate companies or technologies we have acquired or may acquire; intellectual property risks, including but not limited to, infringement litigation; limitations and covenants in our senior credit facility; our need for additional funds to finance our operating needs; volatility and disruption in the global capital and credit markets; acceptance of our products among physicians and other healthcare providers; competition with other providers of diagnostic products; adverse actions or delays in new product reviews or related to currently-marketed products by the U.S. Food and Drug Administration (the "FDA"); changes in government policies; compliance with

other government regulations, such as safe working conditions, manufacturing practices, environmental protection, fire hazard and disposal of hazardous substances; third-party reimbursement policies; our ability to meet demand for our products; interruptions in our supply of raw materials; product defects; business risks not covered by insurance and exposure to other litigation claims; interruption to our computer systems; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations and foreign currency exchange risk sharing arrangements, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, political and economic instability, taxes, and diversion of lower priced international products into U.S. markets; our significant debt service requirements; the possibility that we may incur additional indebtedness; our ability to settle conversions of our convertible senior notes in cash; the effect on our operating results from the trigger of the conditional conversion feature of our convertible senior notes; dilution resulting from future sales of our equity; volatility in our stock price; provisions in our charter documents, Delaware law and our convertible senior notes that might delay or impede stockholder actions with respect to business combinations or similar transactions; and our intention of not paying dividends. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "future," and similar words, although some forward-looking statements are expressed differently. The risks described in reports and registration statements that we file with the Securities and Exchange Commission (the "SEC") from time to time should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this press release. We undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, except as required by law.

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